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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,375	06/19/2001	Eva Turley	7841-106	1481

7590
11/01/2004
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EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/883,375	TURLEY, EVA	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-28 is/are pending in the application.
- 4a) Of the above claim(s) 13-15,27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1646

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II and species election of STMMSRSHKTRSHH in the reply filed on 25 August 2004 is acknowledged. Claims 13-28 are pending in this application. Claims 13-15, 27, and 28 are withdrawn from consideration as being drawn to a non-elected invention. The requirement for an election of species is withdrawn; all species were searched.

Specification

2. The disclosure is objected to because of the following informalities: The brief description of figure 1 does not refer to the sequences of the selected clones by reference to the identification number of an entered sequence. In addition, the sequences on p. 31 lack sequence identifiers. See MPEP §2421.

Appropriate correction is required.

Claim Objections

3. Claims 17-20 and 22-26 are objected to because they contain sequences that are not referred to by the identification number of an entered sequence. See MPEP §2421.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 16-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibition of cell locomotion and of tissue fibrosis using peptides

Art Unit: 1646

consisting of or consisting essentially of those of claims 16-26, does not reasonably provide enablement for methods “modulating” cell locomotion, for methods of preventing fibrosis, or for methods using peptides comprising these sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman*, (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claims 16-20 encompass methods of “modulating” cell locomotion. This term encompasses increases in locomotion as well as decreases. However, what is shown is a decrease. Thus the peptides would not predictably be able to “modulate” locomotion as broadly claimed; they only decrease it. Claims 21-26 encompass “prevention” of fibrosis. What is taught by the specification, however, is that the claimed peptides can reduce fibrosis as measured by effects on contraction (figures 18 and 19); however, substantial contraction does occur. Thus, no guidance is presented to indicate that fibrosis could actually be prevented, only that it could, to a degree, be inhibited. Claims 16-26 encompass methods using peptides comprising generic peptides (claims 16 and 21) or comprising particular species (claims 17-20 and 22-26). However, what is shown is the effect of a single representative peptide. “Comprising” is open language with no requirement that the essential characteristics of the peptide be maintained.

Art Unit: 1646

Sequences comprising this or other peptides could thus be expected to have very different functions; no guidance is provided to indicate what additional sequences could be added without changing the inhibitory nature of the peptides. The prior art fails to provide compensatory teachings; as Applicant indicates on pp. 31-32, other peptides have different characteristics. Thus the claims are broadly drawn to encompass effects that would not predictably occur, as well as methods using a broad genus of molecules that would not predictably have the same characteristics as the disclosed sequences. It would thus require undue experimentation for the artisan to practice the invention as broadly claimed.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

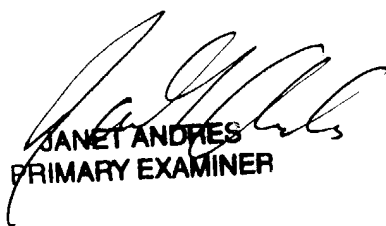
Application/Control Number: 09/883,375

Page 5

Art Unit: 1646

Janet L. Andres, Ph.D.

29 October 2004


JANET ANDRES
PRIMARY EXAMINER